

## Report of the 2<sup>nd</sup> meeting of the JCTLM Executive Committee

13 December 2004, BIPM Sèvres

### List of participants:

Prof J. Thijssen (JCTLM Chairman, IFCC)  
Dr R I Wielgosz (JCTLM Secretariat, BIPM)  
Prof J-C. Forest (IFCC)  
Dr R. Kaarls (BIPM)  
Dr W.E. May (JCTLM WG1 Chair)  
Prof M.Muller (IFCC)  
Dr L. Penberthy (ILAC)  
Dr H. Schimmel (JCTLM WG1 Chair)  
Prof L. Siekmann (JCTLM WG 2 Chair)  
Prof L. Thienpont (JCTLM WG 2 Chair)  
Prof A. Wallard (BIPM)

Apologies received:

Mr A. Squirrell (ILAC)

### Report of meeting:

#### 1. Approval of the agenda [JCTLM-EXEC-04-21]

Prof Thijssen opened the meeting and asked the Committee whether any additional points should be considered for the agenda. Dr Kaarls asked for a discussion of the Quality Manual to be added under agenda point 3.2. Prof Siekmann requested that agenda point 3.1 be extended to address membership of the JCTLM working groups. The changes to the agenda were approved.

#### 2. Report of the 1<sup>st</sup> JCTLM Executive Meeting [JCTLM-EC-01]

Dr Wielgosz brought the Committee's attention to the action points which were listed in the report of the 1<sup>st</sup> meeting of the Committee. He noted that all actions had been completed with the exception of action point (A9) (completed review forms for each material / method had not been sent to the Secretariat) and (A12) (the IFCC advisory group had not yet formulated a quality manual/procedures for the IFCC EQAS rounds).

In the discussion that followed, it was noted that all information related to the review of a method or material would need to be sent to the Secretariat with the adoption of the new material/method review forms in nomination Cycle III.

Prof Siekmann explained that the procedures for the IFCC EQAS were yet to be documented in a quality manual, and he had hoped to employ the procedures used for the CIPM Comparisons as a model for the procedures which would be adopted for IFCC EQAS. Prof Wallard replied that information on how to carry out CIPM comparisons was currently spread among a number of documents, and that the BIPM was currently charged with compiling these into one single procedures document. He expected that the BIPM would have this document ready by mid/end February 2005 and that a copy would be then sent to Prof Siekmann.

**ACTIONS:**

- (A1) All review information related to materials / methods to be sent to the Secretariat with the adoption of the new version of the Materials / Methods nominations template (Cycle III)**
- (A2) BIPM to send L. Siekmann a copy of the procedures document for CIPM comparisons (end February 2005)(sent 15/02/2005)**
- (A3) IFCC advisory group to formulate a quality manual / procedures for IFCC EQAS after receipt of BIPM documents (to be presented to the JCTLM Executive (November 2005))**

3. JCTLM Framework and Declaration of Cooperation [JCTLM-EXEC-04-01]

3.1 JCTLM membership and Working Group Membership [JCTLM-EXEC-04-25]

Dr Wielgosz presented document JCTLM-EXEC-04-25, which listed all organizations that had applied for membership of the JCTLM (in accordance with Appendix IV: Participation of Organizations in the JCTLM). The Executive Committee approved the membership of all listed organizations.

Prof Muller commented that it was important to encourage organizations active in the field to support the JCTLM, and noted that he felt that Asian organizations were under represented, and that a number of Japanese organizations which already been active in the JCTLM had not applied for membership. Dr Wielgosz replied that a letter inviting organizations to be members of the JCTLM was posted on the JCTLM website, and that this would be discussed in the meetings that followed. Dr May replied that he would approach the CAP about JCTLM membership.

Prof Thijssen was pleased to see that organisations were interested in supporting the work of the JCTLM. He stated that a meeting for JCTLM members should be convened once a year, and in future that this would be a combined meeting of the JCTLM Executive, Members and Review Team Leaders. He noted that it would be important for the JCTLM Member Organizations to support the work of the Working Groups, and that the Secretariat should indicate this in correspondence to Members.

Prof Siekmann raised the issue of membership of JCTLM working groups, and the procedure for approving members to these. Dr Wielgosz noted that membership of working groups was ratified by Working Group Chairs and was based on an individual's expertise and willingness to be an active member in a review team. Dr Kaarls stated that the overall responsibility for membership of JCTLM Working Groups remained with the Executive, and that membership of the working groups should also be reviewed by the Executive Committee once a year. Prof. Wallard noted that if needed, statements on membership of working groups in the declaration of cooperation document should be clarified.

**ACTIONS:**

- (A4) Dr May to contact CAP informing them of the activities of JCTLM and encourage their participation.**

- (A5) JCTLM Secretariat to write to Member organizations requesting they support Working Group Review Teams with nominated experts (completed March 2005)**
- (A6) JCTLM Secretariat to review statements on Working Group membership, and develop a clarified statement for Executive Committee approval**

### 3.2 Legal Issues and the Quality Manual

Prof Wallard reported that the BIPM had contacted its lawyers to ask for legal advice on liability issues that may arise from the activities of the JCTLM in listing materials, methods and laboratories. In relation to laboratories, he insisted that the activities of the JCTLM should not be interpreted as those of an accreditation body, and that the JCTLM should limit itself to making statements of fact and not judgements on services offered by laboratories.

Dr Kaarls noted that ILAC and JCTLM Working Group 2 should reach agreement as to which standards laboratories should be making their services compliant.

Dr May stated that the measurement services of laboratories should be referred to, rather like Calibration and Measurement Capabilities (CMCs) within the CIPM-MRA process, rather than the laboratories themselves.

Prof Siekmann proposed that the listing of a measurement service of a laboratory should be based on that service fulfilling specific criteria, and there was general agreement that these were:

- a) that the measurement service is a realisation of a Reference Measurement Procedure (RMP) published in the JCTLM Lists;
- b) and that the laboratory has been accredited for this service or that this service is peer-reviewed through the CIPM-MRA process;
- c) and that the laboratory demonstrates that it maintains this service within its specifications through regular participation in international comparisons.

Prof Siekmann stated that very few laboratories were accredited at this moment in time, and that some sort of transition period should be considered for laboratories that operated measurement services that fulfilled the other two criteria.

Dr Penberthy stated that ILAC had some minor issues with ISO 15195 being the basis for accreditation, but otherwise he supported the principles as outlined by Prof Siekmann.

Prof Siekmann replied that accreditation to 17025 as a calibration laboratory would be acceptable but 17025 accreditation as a testing laboratory would not. Prof Thijssen noted that this was an important statement, and that further discussion and advice from ILAC was required in order to finalise criteria related to accreditation in quality documents developed by the JCTLM.

Dr Kaarls noted that JCTLM quality documentation must be clear and developed in a transparent system and should be read through by the BIPM's legal advisor before publication. He noted the excellent work of the team which had developed the WG1 quality manual, but stated that some inconsistencies were still present in the documentation and these should be revised as quickly as possible.

**ACTIONS:**

- (A7) JCTLM Executive will have quality documents, which are submitted to it for approval, vetted by its legal advisers.**
- (A8) Dr Kaarls to pass on his comments related to the JCTLM Quality Manual to the WG1 Quality Manual Team Leader**

4. Liaison with the EC

4.1 Report of presentation at the MDEG [JCTLM-EXEC-04-19]

Prof Thijssen reported that he and Dr Wielgosz had attended a meeting of the MDEG and presented the work of the JCTLM. Although DG Enterprise was not a JCTLM member it would continue to liaise with the committee.

4.2 Update on liaison with the MDEG

Dr Wielgosz reported that the secretariat had continued its liaison with DG Enterprise. The secretariat had invited members of the MDEG to the JCTLM meetings via DG Enterprise. Unfortunately DG Enterprise would not be represented at this meeting of the JCTLM.

Dr Schimmel reported that he had recently visited DG Enterprise and had discussed the work of the JCTLM. Discussions would continue with the DG Enterprise and would concentrate on how the Commission could officially refer to the recommendations of the JCTLM.

Dr Kaarls stated that it would be useful for both IRMM and the JCTLM to continue discussions on this subject with the Commission.

**ACTIONS:**

- (A9) Dr Schimmel (IRMM) and the JCTLM Secretariat to continue liaison with DG Enterprise and the Commission.**

5. Liaison with the WHO

5.1 WHO materials and the JCTLM lists

Prof Wallard explained that he had recently received a letter from Dr Groth of WHO, who explained that the WHO would not be submitting their materials for publication in the JCTLM lists of higher order materials.

Dr May noted that although the WHO materials would therefore not be published in these lists, biological standards traceable to the WHO materials had been submitted and would be published in the JCTLM lists.

Prof Thijssen remarked that it was important to maintain the liaison with the WHO, as some 50 of the 400 or so WHO materials were important for diagnostic applications.

6. Publicity for the JCTLM

Prof Thijssen stated that it was important to publicise the work of the JCTLM. Dr May, noted that a number of publications were planned, as well as Edutrack Sessions in Clinical

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Chemistry meetings. He added that it would be worth while putting together a powerpoint presentation that could be used to promote the JCTLM. Prof Forest commented that the IFCC would be publicising the JCTLM in its 2005 meetings. Dr Kaarls noted that it was important to inform the accreditors on the work of the JCTLM , and that ILAC should take the lead here.

### **ACTIONS:**

**(A10) Dr May and Dr. Wielgosz to develop a set of powerpoint slides for Executive Committee use to publicise the JCTLM**

### 7. JCTLM Chairman and Secretariat

Prof Thijssen drew the committee's attention to the JCTLM Declaration of Cooperation document which stated that the Chairmanship and Secretariat should be held by IFCC and the BIPM for a period of two years, and that this time period had now passed. Prof Muller noted that in the original discussions it was envisaged that the Chairmanship and Secretariat would rotate amongst the sponsoring organisations. However, he proposed that the current arrangement with the chair from the IFCC and the Secretariat at the BIPM was working well, and should be maintained. Prof Wallard replied that the BIPM was prepared to continue to provide the secretariat for the committee. It was agreed that Prof Thijssen would remain as Chairman of the Committee for another year, at which point the Chairmanship would be reviewed. The IFCC and BIPM agreed that they would share the cost of the JCTLM Secretariat, and the financial contribution of the IFCC to the BIPM had been settled. Contributions for the years 2004 and 2005 would be transferred to the BIPM in January 2005.

### 8. Future meetings of the JCTLM

#### 8.1 Full meeting of the JCTLM and Symposium

Prof Thijssen noted that the JCTLM Stakeholders meeting and Symposium were planned for the next two days.

#### 8.2 JCTLM Executive meeting

Prof Thijssen proposed that a of the Executive Committee should be held at the end of 2005 (November 14 and 15).

### **Proposed timetable of JCTLM meetings 2005:**

Group	Date	Location	Confirmation	Comments
Executive	25 July	IFCC/AACC Orlando USA	tbc	
WG2	27July IFCC/AACC meeting	IFCC/AACC Orlando USA	tbc	
WG1	19-20 September	IRMM	tbc	
WG2	19-20 September	IRMM	tbc	
JCTLM Members	21 September	IRMM	tbc	Executive Committee in

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				attendance
Executive	14-15 November	BIPM	tbc	

tbc= to be confirmed

### **ACTIONS:**

**(A11) JCTLM Secretariat to confirm dates of next JCTLM meetings**

R.I. Wielgosz (BIPM)  
17 December 2004  
revised 7 March 2005

**Annex 1: Summary List of Actions**

- (A1) All review information related to materials / methods to be sent to the Secretariat with the adoption of the new version of the Materials / Methods nominations template (Cycle III)**
- (A2) BIPM to send L. Siekmann a copy of the procedures document for CIPM comparisons (end February 2005)**
- (A3) IFCC advisory group to formulate a quality manual / procedures for IFCC EQAS after receipt of BIPM documents (to be presented to the JCTLM Executive (November 2005))**
- (A4) Dr May to contact CAP informing them of the activities of JCTLM and encourage their participation.**
- (A5) JCTLM Secretariat to write to Member organizations requesting they support Working Group Review Teams with nominated experts**
- (A6) JCTLM Secretariat to review statements on Working Group membership, and develop a clarified statement for Executive Committee approval**
- (A7) JCTLM Executive will have quality documents submitted to it for approval vetted by its legal advisers.**
- (A8) Dr Kaarls to pass on his comments related to the JCTLM Quality Manual to the WG1 Quality Manual Team Leader**
- (A9) Dr Schimmel (IRMM) and the JCTLM Secretariat to continue liaison with DG Enterprise and the Commission.**
- (A10) Dr May and Dr. Wielgosz to develop a set of powerpoint slides for Executive Committee use to publicise the JCTLM**
- (A11) JCTLM Secretariat to confirm dates of next JCTLM meetings**

**Agenda for the 2<sup>nd</sup> JCTLM Executive Meeting**  
**Date of meeting: 13 December 2004**  
**Time: 8.00 am to 10.00am**

1. Approval agenda
2. Report of 1<sup>st</sup> JCTLM Executive Meeting
3. JCTLM Framework and Declaration of Cooperation
  - 3.1 JCTLM membership
  - 3.2 Legal issues
4. Liaison with the EC
  - 4.1 Report of presentation at the MDEG
  - 4.2 Update on liaison with the MDEG
5. Liaison with the WHO
  - 5.1 WHO materials and the JCTLM lists
6. Publicity for the JCTLM
7. JCTLM Chairman and Secretariat
8. Future meetings of the JCTLM
  - 8.1 Full meeting of the JCTLM and Symposium
  - 8.2 JCTLM Executive meeting
9. Any other business



**Points arising from the JCTLM Executive Committee and Working Group Review Team Leaders Meeting(13 December 2005)**

**Present: JCTLM Executive Committee  
JCTLM Working Group Review Team Leaders**

1. The JCTLM WG1 Quality manual had been approved and was published in September 2004 on the JCTLM webpages.
2. List II reference materials from the Cycle I nomination process were approved for publication in the JCTLM lists [expected publication date January 2005].
3. The Secretariat will review the web site contact forms to ensure interested parties can comment on published JCTLM lists.
4. The comparability of reference measurement methods should be established, and the IFCC comparisons will provide a vehicle to do this. However, at present this is not a formal process described within the JCTLM WG1 quality manual (Action: Quality Manual Review Team to address in revised manual).
5. The quality manual currently does not address the issue of regular (re)reviews of published materials and methods. This should be addressed in the next update of the manual. (Action: Quality Manual Review Team to address in revised manual)
6. If the producer's stocks of a reference material are depleted, the material should not be delisted (since a customer may still have stocks of the material), rather a comment should be inserted that the producer's stock of the material is depleted. The quality manual review team shall recommend whether changes to the quality manual are required. (Action: Quality Manual Review Team to address in revised manual)
7. The JCTLM will need to address the issue of sustainability of the reference material comparability studies required by the quality manual.
8. Differences exist between the requirements of ISO Guide 34 and ISO 15194 for reference materials. This will need to be addressed in the rewrite of ISO 15194, which is foreseen in 2 years. (Action: JCTLM Secretariat to inform ISO of differences)
9. There is currently a mismatch between nominated reference materials and reference measurement procedures in a number of categories. This needs to be addressed by JCTLM WG1.
10. The Reference measurement procedures which have been submitted for JCTLM review are generally publications in peer reviewed journals. SOPs of particular laboratories (for which ISO 15193 is directly applicable) are not being reviewed by the JCTLM. This difference needs to be explained with the JCTLM quality manual. (Action: Quality Manual Review Team to address in revised manual)

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11. In the case of procedurally defined measurands the JCTLM shall make a clear statement on whether National Reference Procedures shall be published in the JCTLM lists in the case where there is no Internationally agreed Reference Procedure, and also in the case where an Internationally agreed Reference Procedure exists. (Action: JCTLM Executive to issue a policy statement).
12. A number of the analytes in the JCTLM lists are also important in the fields of Forensics and Sports Drugs testing. A clear statement shall be made by the JCTLM that it is making no recommendation on the applicability of the listed reference measurement procedures in the fields of forensics or sports drug testing.
13. The IFCC is to advise the JCTLM Secretariat and WG1 on the criteria it uses when considering whether measurement procedures developed by commercial producers are candidates for IFCC endorsement as reference measurement procedures.
14. JCTLM WG1 is to consider what actions are necessary when two or more List II reference materials are nominated for publication, for nominally the same analyte, but whose values are traceable to different Conventional International Standards.
15. JCTLM WG1 should recommend whether or not a statement of intended use of each reference material should be published within the JCTLM lists
16. A new version of the materials and methods nominations template will be brought into use for Cycle III nominations (April 2005)
17. The complete excel nominations sheets for Cycle I and II will need to be forwarded for all materials and methods to the JCTLM Secretariat, to enable development and publication of a web searchable JCTLM database (by February 2005)
18. JCTLM Working group II lists should refer to measurement services offered by laboratories.
19. Laboratories that claim that their measurement services are underpinned by the CIPM-MRA process shall be required to have a published CMC (calibration and measurement capability) which covers the range of this claimed service.
20. Any statement on the measurement services offered by laboratories should be a statement of fact, i.e.: these services are based on a JCTLM listed reference measurement procedure; the laboratory has been accredited for this measurement service or has a published CMC in the CIPM-MRA that covers this service; participates regularly at an appropriate level in international comparisons, demonstrating its ability to deliver the measurement service.
21. A link from the JCTLM webpages to the IFCC ring trial results page is to be established.

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R.I. Wielgosz (BIPM)  
22 December 2004  
revised 7 March 2005